REMARKS

Claims 33 and 63 have been amended to improve the description of how the flap is pressed towards the seal surface in an abutting relationship with it.

Claims 33-71 have been rejected for double patenting over a number of copending applications. Applicants' invention requires a valve seat and a single flexible flap. The flexible flap is secured to the valve seat at the flap's stationary portion at two securement points. The Examiner has not identified any other patent or allowed patent application that claims this feature of applicants' invention.

As the Examiner is aware, a double patenting rejection can only be sustained if the applicant is claiming the same invention that has been claimed in a patent or in a patent application that is about to issue as a patent or if the applicant is claiming an invention that would have been obvious in view of an invention that is being claimed in such a document. In making this double patenting rejection, the Examiner has not indicated whether the double patenting rejection is made under 35 USC § 101 or made under the judicially-created doctrine of obviousness type double patenting. Because none of the claims that are presented in this case are identical to the claims in any of applicants' copending applications or issued patents, applicants assume, in making the following argument, that the claims have been rejected based on obviousness-type double patenting.

A double patenting rejection cannot be sustained for obviousness-type double patenting when no evidence has been presented to demonstrate that applicants' claimed invention is obvious over an invention claimed in any issued patent or allowed patent application. As the Examiner is aware, obviousness-type double patenting is a judge-made doctrine that prevents an extension of the patent right beyond the statutory time limit. This type of rejection can only be sustained when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly-owned patent.[1] The purpose of the doctrine is to prevent an unjustified patent term extension by allowing a second patent to issue what claims an obviousness variant of the already-patented invention.[2] Generally, a "one-way" test has been applied to determine whether an obviousness-type double patenting rejection can be sustained. Under this test, the Examiner is supposed to ask whether the application claims are obvious over the patent claims.[3] If the

[1] *In re Bratt*, 19 USPQ2d 1289, 1291-92 (Fed. Cir. 1991).
[2] *In re Goodman*, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993).
[3] *In re Berg*, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998).

application claims are patentably distinct from the claims in the issued patent, then the double patenting rejection is not proper and must be withdrawn. If, however, the application is not patentably distinct, then the applicant can file a Terminal Disclaimer to eliminate the issue with respect to double patenting.[4]

It is incumbent upon the United States Patent and Trademark Office to clearly explain the reasons behind its rejection of a claim.[5] Besides not furnishing applicants with the statutory basis for this rejection, the Examiner also has yet to identify any claim in any of applicants' patents (or any allowed copending application), which suggests a flexible flap that is secured to a valve seat at two securement points. Until the Examiner can show where this feature, or an exhalation valve that is obviously similar, is also being claimed by appellants, the obviousness-type double patenting rejection cannot be properly sustained. Presently, the Examiner has only cited all the claims that are in applicants' copending applications. In the absence of evidence demonstrating how the subject matter claimed in this application would have been obvious over the subject matter claimed in those copending cases, the double patenting rejection is not proper.

In any event, the Examiner has not allowed any claims in any of applicants' copending applications. Until such claims have been allowed and those claims have issued, the double patenting rejection is premature. You cannot terminally disclaim subject matter over a patent application that may never issue as a patent. Thus, any double patenting rejection can only be made provisionally, MPEP § 804 I.B., 800-19 (August 2001).

Claims 33-56, and 63-69 have been rejected under 35 USC § 103(a) as being unpatentable over U.K. Patent Application GB 2,072,516A to Simpson in view of U.S. Patent 3,191,618 to McKim. Applicants respectfully submit that this rejection cannot be sustained for the following reasons.

Firstly, the subject matter of applicants' invention is structurally and functionally dissimilar to the subject matter described in Simpson. Applicants' invention requires a *flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when no external forces from the*

[4] *In re Berg*, 46 USPQ2d at 1229.

[5] *See, e.g., In re Mindick*, 152 USPQ 566, 567 (CCPA 1967) ("As a general rule, we think examiners and the board have an obligation to state with precision the statutory basis for a rejection, unless the basis is otherwise clear from the terms used."); *see also In re Herrick*, 145 USPQ 400, 402 (CCPA 1965) ("Patent Office tribunals need to

movement of fluid are exerted upon the flap. Applicants' invention further requires a *flexible flap also being secured to the valve seat at the stationary portion of the flap at two securement points*. Simpson shows a flap-retaining surface and seal surface that are in direct alignment with each other. When closed, the Simpson flap would remain flat in planar alignment with its flap-retaining surface and its seal surface. It would not be *pressed* against the seal surface when a wearer of the mask is neither inhaling or exhaling. An expert in the field of respirators and respirator components, David M. Castiglione, has provided evidence that establishes that the valve 13 shown in Figure 2 of Simpson does not have its flap 15 *pressed* against the seal surface in an abutting relationship with it when a wearer would be neither inhaling nor exhaling. Castiglione states in paragraph 9 of his February 2, 2001 Affidavit (Exhibit A) that "there is nothing that can be discerned from Figure 2 [of Simpson] or from the [Simpson] specification that would indicate that the flap is pressed towards the seal surface in its neutral position." Another expert in the field of exhalation valves, John Bowers, (the inventor named in U.S. Patent 5,687,767) stated the following with respect to Simpson in paragraph 15 of his Declaration dated December 10, 2001 (Exhibit B):

> My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

Given the aligned relationship between the flap retaining surface and the seal surface, there is no force exerted upon the flap that would bias the flap against the seal surface. The flap 15 can only reside in mere contact with the seal surface in the closed position. Simpson therefore places the exhalation valve 12 on the top portion 1 of its pouch-shaped mask (see Fig. 1 of Simpson) so that gravity can hold the valve shut when the wearer is neither inhaling nor exhaling. Gravity, however, does not constitute positioning the flap on the valve seat *such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when no*

sufficiently explain the reasons for the rejection to permit a proper determination of the outstanding issue"); *In re Chilowsky*, 108 USPQ 321, 326 (CCPA 1956).

external forces from the movement of fluid are exerted upon the flap. In addition, Simpson does not teach or suggest the use of two securement points for mounting the flap to the valve seat.

Secondly, the secondary reference to McKim cannot be applied as prior art against applicants' invention because the McKim patent does not describe technology in an analogous art. Title 35, Section 103, of the United States Code requires that documents relied upon for obviousness must be "in the art to which said subject matter pertains." In other words, the art must be analogous to the "subject matter sought to be patented."[6] As the Examiner is aware, a reference cannot be considered sufficiently analogous and thus relevant for determining obviousness unless it is either (1) within the field of the inventor's endeavor, or (2) is reasonably pertinent to the particular problem that confronted the inventor.[7] Applicants' invention resides in the field of filtering face masks that use exhalation valves. McKim does not reside within this field of endeavor: it resides in the field of gasoline engines that use reed valves.

McKim shows a curved seat reed valve that is designed for use in a 2-cycle engine, which would turn at speeds as high as 10,000 or 12,000 revolutions per minute. In contrast, applicants' invention pertains to a filtering face mask that employs an exhalation valve, which opens in response to a wearer's breathing. Castiglione explained in his November 15, 1999 Affidavit (Exhibit C) why McKim does not reside in the field of endeavor of applicants' invention:

> The field of endeavor for a filtering face mask is very different from the field of endeavor of a curved seat reed valve that is used in a high-speed engine. Persons of ordinary skill in the field of designing filtering face masks do not consult documents that describe valves for gasoline engines in developing respiratory products. Exhalation valves for respirators operate under very different conditions from valves that are used in gasoline engines and require extraordinary different design parameters.

Another investigator who works in the filtering face mask field, John L. Bowers, explains why McKim is not in the field of endeavor of a person of ordinary skill in the art designing exhalation valves:

> My review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which could turn at speeds as possibly as high as 10,000 or 12,000 revolutions per minute (rpm). The reed valve described in McKim is indicated to be particularly suited for a high speed operation where

[6] 35 USC § 103(a).
[7] *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

opening and closing forces are large. McKim states these forces can cause the valve to bounce (an apparent elastic recoil from impact). The stated goals in McKim are full and rapid opening, quick and complete closing, and eliminating float and bounce.

The field of the above-captioned '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow warm, moist, exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves generally operate at normal room temperatures and pressures.

The field of endeavor for filtering face mask is very different from the field of endeavor of a reed valve that is used in a two-cycle engine. Exhalation valves for respirators operate under very different conditions from valves that are used in two-cycle engines and require notably different design parameters. The valve that is described in McKim has very rapid opening and closing requirements (thousands of openings and closings per minute) and operates under temperatures and pressures that differ substantially from the requirements of exhalation valves, which open and close under the much slower pace of a wearer's breathing and under temperatures and pressures that tend to vary only from the ambient to that exhibited by the wearer's exhaled air. Thus, persons of ordinary skill in the field of designing filtering face masks, to the best of my knowledge and experience, do not find valves for two-cycle engines to be in their field of endeavor and therefore do not consult documents that describe valves for these engines when developing new respiratory products.

Bowers' Affidavit, paragraphs 11-13 (Exhibit B). Another person skilled in the field of exhalation valves for filtering-face masks, Frank Fabin, who has worked on one design team and led another design team in the development of a new exhalation valve, stated the following with respect to McKim:

My review of the McKim patent reveals a curved seat reed valve that is suitable for use in high rpm two-cycle engines. The reed valve comprises a thin, normally flat, single thickness, springy, sheet material, which, when relieved of external stresses will lie flat, but which is flexed lengthwise to define a curve. The reed valve is disclosed to be made of a spring sheet material, such as, for example, shim stock. The reed valve is disclosed to bear throughout its length against a valve seat, with the seating bias at the free end of the reed being as great as, or greater than, that throughout the remainder of the reed. The reed valve is indicated to be designed to seat quickly, effectively, and without float or bounce after each opening. The patent indicates that the reed valve is adaptable for use within an extremely high-speed engine, for example, one that will turn at a speed on the order of 10,000 or 12,000 revolutions per minute or at more modest speeds of 5,000 to 6,000 rpms.

> In my approximately 24 years of working in occupational health, I have not — nor am I aware of another person who works in this field who has — consulted a reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks.
>
> Filtering face masks posses the problem of creating a warm, moist, high CO_2 content environment around the nose and mouth of a person who wears a filtering face mask. Investigators in this field have pursued a goal of purging from the mask interior the largest amount of fluid possible while using the least amount of energy. Investigators therefore have pursued the particular goal of designing exhalation valves that open easily in response to the exhalation pressure developed in the mask interior during an exhalation. Exhalation valves that open under minimal pressure allow the warm, moist high CO_2 content air, to be more easily removed from the mask interior and thus require the wearer to expend less energy to operate the valve over an extended period of time. Exhalation valves typically operate under ambient environmental conditions in response to exhalation pressures generated by the wearer. These conditions are remarkably different from the environment (for example, temperatures and pressures) under which a reed valve operates in a two-cycle gasoline engine. The flexible flaps that are used in exhalation valves do not deal with problems of float, or flutter from bounce in closing like the reed valves described by McKim. The opening and closing of an exhalation valve occurs in cadence with a wearer's breathing pace, which is orders of magnitude less than the high rpms under which gasoline engines operate at. For these reasons and others, persons of ordinary skill in the filtering face mask and exhalation valve art, as far as I am aware, do not examine documents that pertain to reed valves for two-cycle gasoline engines in designing filtering face masks and the exhalation valves that are used on them. Documents that describe reed valves for two-cycle gasoline engines are not in the field of endeavor of persons who design exhalation valves for filtering face masks.

Fabin Affidavit, paragraphs 8-10 (December 10, 2001) (Exhibit D). In view of all this evidence, it is clear that the McKim patent does not reside in the field of endeavor of a person who designs exhalation valves for use on filtering face masks. Because the Examiner has not put forward any evidence to the contrary, the only conclusion that can be reached is that the McKim patent is not in applicants' field of endeavor.

Since the first element of the two-part test for evaluating whether a reference is analogous has not been satisfied, it therefore is necessary to consider whether the McKim reference is reasonably pertinent to the particular problem that concerned the applicants. The Federal Circuit has explained that the **USPTO needs to consider the purposes of the reference disclosure and the invention** in determining whether a reference meets the second prong of the two-part test:

> A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it** (emphasis added).[8]

In developing their invention, applicants sought to produce an exhalation valve that minimized the exhalation pressure to open the valve and allowed a greater percentage of exhaled air to be purged through the exhalation valve to improve wearer comfort (see applicants' specification at page 3, line 25 to page 5, line 34 and Examples 4-6 and 8-13). The McKim reference, however, deals with solving the problem of float or bounce, which may occur when a 2-cycle engine is operating at high rpms (see McKim at column 1, lines 20-24 and column 2, lines 55-62). McKim's concern for controlling float or bounce is not reasonably pertinent to the problems that applicants were involved with — namely, providing comfort to the mask wearer by allowing the valve to open under minimal pressure and enabling a greater percentage of exhaled air to be purged through from the mask interior through the valve. As stated in the Bowers Declaration, investigators who work in the field of exhalation valves for filtering face masks are not concerned with problems of float or bounce:

> In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow

[8] *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

> volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

The Castiglione and Fabin declarations discussed above also explain how McKim is concerned with a problem that is of no concern to the purpose of the present invention. Because the purpose of appellants' invention is not pertinent to the problem that McKim dealt with, namely float or bounce, the second prong of the test for qualifying as an analogous reference also has not been met. A person possessing ordinary skill in the art of filtering face masks that use exhalation valves would not reasonably have been expected to solve the problem of lowering the airflow resistance force needed to open an exhalation valve through considering a reference that deals with eliminating float or bounce of a valve reed in a 2-cycle gasoline engine. As such, the obviousness rejection based on McKim cannot be properly sustained.

Thirdly, even if McKim was found to be an analogous reference, a person of ordinary skill still would not have been led to applicants' invention because the structure of the reed valve disclosed in McKim would not answer the required properties of appellants' valve. There is no evidence that the McKim reed valve would demonstrate the required flexibility of appellants' flexible flap. Appellants have defined the term "flexible" to mean that "the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see, e.g., Fig. 5)."[9] The flap that is described in McKim is made of "spring sheet material, such as, for example, shim stock" (column 1, lines 59-61). McKim therefore is not describing a flexible flap that would be suitable for use in an exhalation valve. This fact is confirmed by Richard Betts, a person skilled in the art of two-cycle engines:

> Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the

[9] Appellants' specification at page 7, lines 11-14.

> above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

Declaration of Richard Betts, paragraph 5 (December 7, 2001) (Exhibit E). Because McKim's valve reed is so structurally different from the flexible flap that is used in the present invention, there would be no reason to expect — and there is no evidence in this record to indicate otherwise — that McKim's method of mounting its stiff valve reed would be suitable for a more highly flexible flap that is used on an exhalation valve. Further, the conditions under which the McKim reed valve operates (high pressure, high temperatures, 10,000 or so cycles per minute) is so remarkably different from the conditions under which an exhalation valve operates (lung pressure, exhaled air temperatures, and breathing cycles of 20-60 per minute), that there can be no expectation that any structure described in McKim would be suitable to produce an invention like the one under consideration here. Thus, the mounting requirements for the McKim valve cannot be transferred to an exhalation valve like Simpson's without some clear teaching or suggestion to do so.

Fourthly, the record is devoid of any teaching, suggestion, or motivation to combine the pertinent teachings of Simpson and McKim. As the Board is aware, an obviousness rejection cannot be sustained, based on a combination of references, without any evidence of why a person of ordinary skill would have been motivated to combine the pertinent teachings.[10] The suggestion to make the combination must come from the prior art.[11] It is not enough to simply identify each claimed element in the prior art.[12] "The factual inquiry whether to combine references must be

[10] *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) ("When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.").
[11] *In re Beattie*, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) ("The question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.").
[12] *Rouffet* at 1457. ("If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the

thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."[13]

Simpson's teachings are mainly concerned with producing a face mask that is in the shape of a pouch and that has an exhalation valve. Simpson's valve teachings are not concerned so much with showing how to make a low pressure drop valve that can remain closed under a variety of orientations as they are concerned with simply illustrating alternative valves that could be used on its pouch-shaped mask. And McKim's teachings are for providing a curved reed valve seat on a 2-cycle gasoline engine to reduce float or bounce. The Examiner has not furnished the record with any evidence that shows why a person of ordinary skill would have combined the teachings of each of these documents. The Examiner's maintenance of the rejection without citing any evidence to support the combination is clear legal error. The Federal Circuit has explained at length in *In re Lee* that obviousness rejections based on combinations of references are improper when there is no evidence within the four corners of the record, to support the reasoning behind making the combination.[14]

Until there is evidence in the record, which evidence clearly shows that a person of ordinary skill would have combined the teachings of Simpson with McKim, the obviousness rejection based on these references cannot be properly held to constitute a *prima facie* case of obviousness.[15]

Fifthly, the Simpson and McKim documents each present very good evidence of a lack of motivation to combine their respective teachings. The McKim technology was known to persons of ordinary skill before the Simpson publication. Nonetheless, Simpson did not employ the McKim technology in its flapper-style exhalation valve, even though Simpson and McKim both disclose

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claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability.").

[13] *In re Lee*, 61 USPQ 1431, 1433 (Fed. Cir. 2002).

[14] *See In re Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation" would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority."); *see also In re Dembiczak*, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence'.").

[15] *See Lee* at 1458. (The Federal Circuit reversed a decision of the Board because it "did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.").

flapper-style valves (albeit in entirely different fields). If the use of the particular structure necessary for causing the flap to be pressed towards the seal surface would have been obvious to a person of ordinary skill in making a flapper-style exhalation valve, you would have expected a person skilled in the exhalation valve art to have used that technology in a valve like Simpson's. The Examiner should notice that a very long time has passed since McKim's publication in 1962 and its disclosure of a curved flapper-style valve, but that particular technology did not find its way into use in the exhalation valve art at any point over this large time span. If this aspect of the present invention would have been obvious to a person of ordinary skill, the skilled artisan in the respirator art would have been expected to employ it sometime within those years. A prolonged existence of unused technology provides very good evidence of nonobviousness.[16] Simpson, which was published almost 20 years after McKim and filed more than about 12 years before the effective filing date of the present application, also did not use this technology or find it to have been obvious. Nor did any other investigator in the filtering face mask art, either prior to or after Simpson (but before applicants' invention). Thus, the prior knowledge of the McKim technology and the long time that has elapsed since McKim's first publication, coupled with the failure to use this technology in a flapper valve system, presents very good evidence that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.[17]

Sixthly, the prior art also fails to teach or suggest the advantages that applicants' invention can provide. An invention's advantages must be considered under the "invention as whole" concept set forth in 35 USC § 103.[18] Advantages that are not appreciated by the prior art also provide very good evidence of nonobviousness.[19] In the present case, applicants' invention possesses the benefit of achieving a low pressure drop valve while preventing the influx of

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[16] *See Al-Site Corp. v. Opti-Ray Inc.*, 28 USPQ2d 1915, 1922 (E.D.N.Y. 1993) ("Second, the prior art existed for many years and yet those skilled in the art never created a hanger mechanism comparable to Al-Site's patented invention. See *id.* at 1577."); see also, *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1604-05 (Fed. Cir. 1987) ("We cannot see why the district court's first set of findings did not require a conclusion that Caveney's inventions, which had for years escaped others who sought them, "would not have been obvious" under § 103; nor why Panduit and Dennison wasted research resources for years if Caveney's inventions were obvious to all throughout those years; nor how the prior art made Caveney's eminently successful inventions obvious to the court in 1984 when it had not made them obvious to skilled engineers (each more skilled than the 'ordinary mechanic' referred to in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 261, 13 L.Ed. 683 (1851)) who had been designing unsuccessful or far less successful cable ties for years when Caveney's inventions were made in the 1960's.").

[17] *See In re Ehringer*, 146 USPQ 31, 37, CCPA (1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag *thoriated* tungsten filament or any way of producing it.").

[18] *In re Papesch*, 137 USPQ 43 (CCPA 1963).

contaminants through the valve under any orientation. Simpson's valve, however, only protects to the wearer at the most critical time — during an inhalation. When a wearer of the Simpson mask inhales, the flap becomes firmly pressed against the seal surface. But when the wearer is neither inhaling nor exhaling, and has their head tilted downward, gravity can cause the flap to droop away from the seal surface. Simpson's valve may allow contaminants to enter the mask interior in this instance. To counter this problem, Simpson mounts its valve on the top of the mask body so that gravity can be used to keep the flap closed under neutral conditions. If the valve was mounted to the underside of the mask, the flap would dangle away from the seal surface. The Simpson valve, unlike applicants' invention, therefore, has limited suitable mounting positions on its mask body. And, even if it was mounted to the top of the mask body, it could still allow contaminants to enter the mask interior when the user fully tilts their head downward.

Applicants teach persons of ordinary skill how to make a low pressure drop flapper-style exhalation valve that will preclude contaminant influx under all orientations of the mask. This is achieved by the positioning of the flap on the valve seat and by the flap being pressed against the seal surface under neutral conditions. Applicants' valve also does not have to be disposed on the top side of the mask like Simpson. Applicants' invention, therefore, enables the valve to be disposed on the mask directly in the path of the exhale flow stream — that is, centered on the front of the mask (see Fig. 1) — so that the valve can use the full momentum of the exhaled air stream to lift the flap from the seal surface.

As indicated in paragraphs 15 and 16 of the Bowers Declaration (Exhibit B), the Simpson flap would droop open when the wearer tilts their head downward:

> My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

[19] *See, e.g., In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1989) (Advantages not appreciated by prior art.).

> The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

The failure of Simpson to appreciate the benefits of applicants' invention and instead teach a more deficient construction further establishes the nonobviousness of applicants' invention. McKim, of course, does not address these benefits to the slightest degree because it is a reference that resides in an entirely different field and deals with entirely different problems under entirely different conditions. In short, the prior art does not teach or suggest the construction of applicants' valve, and it does not appreciate the benefits that that construction invention can provide. Under such circumstances, Simpson and McKim would have rendered applicants' invention obvious to a person of ordinary skill within the meaning of 35 USC § 103.

In short, appellants' invention would not have been obvious to a person of ordinary skill because the primary reference to Simpson fails to teach or suggest a number of the basic elements of applicants' invention. Simpson does not have the flexible flap positioned on the valve seat *such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when no external forces from the movement of fluid are exerted upon the flap*. Simpson therefore places its exhalation valve on the top portion of its pouch-shaped mask so that gravity can keep the flap closed under neutral conditions. In this position, however, Simpson's valve can fog the wearer's eyeglasses, and it cannot take the best advantage of the momentum of the exhaled airflow to open the valve. Simpson also does not teach or suggest a flexible flap that is *secured to the valve seat at the stationary portion of the flap at two securement points*. Further, the secondary reference to McKim is not applicable prior art because it is not analogous. In addition, McKim does not describe a flexible flap, and the record clearly shows that a person of ordinary skill in the exhalation valve art would not have been concerned with McKim's goals of controlling float and bounce of a reed valve. Moreover, the record is devoid of any teaching, suggestion, or motivation to combine the teachings of Simpson and McKim. Indeed, Simpson and McKim present very good evidence for a lack of motivation to combine their teachings because McKim's technology was never mentioned in Simpson or any other exhalation valve document despite it being known for many years. Finally, the prior art documents also do not teach or suggest the benefits that applicants' invention may provide. All of these factors establish that applicants'

invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.

Claims 58-62, 70, and 71 have been rejected under 35 USC § 103 as being unpatentable over Simpson in view of McKim and further in view of U.S. Patent 812,706 to Warbasse in combination with U.S. Patent 4,934,362 to Braun. Applicants respectfully submit that this rejection cannot be sustained for the reasons presented above.

Although U.S. Patent 812,706 to Warbasse (published in 1906) has been referenced for teaching a valve cover that has a fluid-impermeable ceiling that increases in height in the direction of a flexible flap from a first end to the second end, Warbasse does not suggest the use of such a valve cover on an exhalation valve that is used in a filtering face mask that is adapted to fit over the nose and mouth of a person. Warbasse describes a device that is placed over a person's nose and is connected to a supply line tube 16. No teaching or suggestion has been identified, which would have motivated a person of ordinary skill to use Warbasse's hood element 11 in the Simpson valve shown in Figure 2. The Examiner indicates that "it would have been obvious to modify the valve (figure 2) of Simpson et al. to provide a valve in this (fig. 2) to provide a valve cover because it would have provided a means for protecting the valve flap (12), controlling the extent of movement of the valve flap, controlling the direction of fluid flow exiting the mask via the valve as taught by Warbasse." *Although there may be a variety of reasons for using a valve cover on the valve shown in Simpson, the Examiner has not yet identified any particular suggestion of why a person of ordinary skill would have selected the hood element 11 in Warbasse's nose device for use on the exhalation valve shown in Figure 2 of Simpson.* As the Examiner is aware, the United States Patent and Trademark Office has the burden of providing *evidence* that shows why a person or ordinary skill would have combined the teachings in two different references. Mere conclusory statements generated by the Examiner do not qualify as evidence. In this regard, the Examiner's attention is again directed to *In re Lee* where the Federal Circuit explained that the motivation to combine references is a factual question that cannot be resolved on subjective beliefs of unknown authority.[20]

The Examiner states that his reasons for combining Warbasse with Simpson are taught by Warbasse. But a review of this patent reveals that none of these reasons can be found anywhere in

Warbasse. Some of those reasons, however, can be found in applicants' specification. For example, applicants state that the exhalation valve, "can be provided with a valve cover to protect the flexible flap" (see applicants specification, page 14, lines 33-35). Applicants also explain that the valve cover can allow the exhaled air to be "directed downwards to prevent fogging of the wearer's eyewear" (see applicants' specification at page 15, lines 5-8). It is, of course, improper to use applicants teachings against them in attempting to establish that a person of ordinary skill would have been led to the combination of references.[21] Perhaps these reasons may have been known in the art before applicants' filing date, but even so, the record still does not establish why a person of ordinary skill would have been motivated, in particular, to use Warbasse's hood element 11 on Simpson's valve over any of the multitudes of value covers that had been previously described in the art.

Respectfully submitted,

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Date

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Enclosures:
Exhibit A - Affidavit of David M. Castiglione of February 2, 2001
Exhibit B - Declaration of John L. Bowers of December 10, 2001
Exhibit C - Affidavit of David M. Castiglione - November 15, 1999
Exhibit D - Affidavit of Frank J. Fabin of December 10, 2001
Exhibit E - Declaration of Robert Betts of December 7, 2001

[20] *See In re Lee*, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002) ("This factual question of motivation [to combine the references] is material to patentability and could not be resolved on subjective belief and unknown authority.").
[21] *In re Lee*, 61 USPQ2d at 1434 ("It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to '[use] that which the inventor taught against its teacher.'"; *see also, W.L. Gore v. Garlock, Inc.*, 721 F2d 1540, 1553, 220 USPQ 303, 312-313 (Fed. Cir. 1983).

VERSION WITH MARKINGS TO SHOW CHANGES MADE

33. (amended) A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface; and

(ii) an orifice that is circumscribed by the seal surface; [and

(iii) cross members that extend across the orifice to create a plurality of openings within the orifice; and]

(2) a single flexible flap that has a fixed portion and only one free portion and first and second opposing ends, the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during an exhalation, and the second end being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when no external forces from the movement of fluid are exerted upon the flap [a fluid is not passing through the orifice], the flexible flap being secured to the valve seat at the fixed portion of the flap at two securement points, the two securement points being disposed outside a region encompassed by the valve seat orifice.

63. (amended) A filtering face mask that comprises:

(a) a mask body that is adapted to fit over the nose and mouth of a wearer; and

(b) an exhalation valve that is attached to the mask body, the exhalation valve comprising:

(1) a valve seat that comprises:

(i) a seal surface;

(ii) an orifice that is surrounded by the seal surface; and

(2) a single flexible flap that has a stationary portion and only one free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the single flexible flap's peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment of the peripheral edge being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free portion also being located below the stationary portion when the filtering face mask is worn on a person, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when no external forces from the movement of fluid are exerted upon the flap [a fluid is not passing through the orifice], the flexible flap also being secured to the valve seat at the stationary portion of the flap at two securement points.